## JAPT Rec'd PCT/PTO 02 JUN 2006

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hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Rexandria, VA 22313-1450.

Dated: May 31, 2006 Signature:

Docket No.: BII-001.01

(PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(Merlin Aubourg)

In re Patent Application of:

Roy R. Lobb

Application No.: 10/521,513

Filed: July 17, 2003

For: THERAPIES FOR RENAL FAILURE

USING INTERFERON-BETA-1

Confirmation No.: 2848

Art Unit: N/A

Examiner: Not Yet Assigned

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)) and thus no fees are believed to be due in connection with this submission.

Applicant has not submitted copies of cited U.S. patents or U.S. patent applications. However, Applicant submits herewith copies of foreign and non-patent references. The examiner

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should note that since reference BA (WO 01/77137) is over 2,000 pages, it is being provided on CD-R in lieu of a printed paper copy.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Applicant has also cited for the Examiner's consideration certain co-pending U.S. patent applications. The co-pending applications are listed herewith in accordance with M.P.E.P. § 609.06 which states: "Applicants may wish to list U.S. patent application numbers on other than form PTO-1449 or PTO/SB/08A and 08B format to avoid the application numbers of pending applications being published on the patent. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact as noted in MPEP § 609.05(b)." No copies of the co-pending applications have been provided. If the Examiner wishes to have copies of the co-pending applications, Examiner should contact the Agent of record.

U.S. Application No.	First Named Inventor	Filing Date	Examiner Initials
10/868,673	A. Whitty	06-15-2004	
10/802,540	B. Pepinsky	03-16-2004	
10/892,830	K. Lin	07-16-2004	
10/529,522	A. Sandrock	09-26-2003	
10/095,496	R. Lobb	03-12-2002	
10/397,108	M. Dibiase	03-24-2003	
Examiner Signature:		Date Considered:	

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-1448, under Order No. BII-001.01.

Dated: May 31, 2006

Respectfully submitted,

Chad E. Davis

Registration No.: 56,179 FOLEY HOAG LLP 155 Seaport Blvd

Boston, Massachusetts 02210

(617) 832-1766 Agent for Applicant





PTO/SB/08a/b (07-05)
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(Use as many sheets as necessary)

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Complete if Known		
Application Number	10/521,513	
Filing Date	July 17, 2003	
First Named Inventor	Roy R. Lobb	
Art Unit	N/A	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	BII-001.01	

	U.S. PATENT DOCUMENTS				
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials*	No.1	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Figures Appear
	AA*	US-5,908,626	06-01-1999	Chang et al.	
	AB*	US-6,127,332	10-03-2000	Goelz et al.	
	AC*	US-4,588,585	05-13-1986	Mark et al.	
	AD*	US-5,565,335	10-15-1996	Capon et al.	
	AE*	US-6,800,735-A1	10-05-2004	Whitty et al.	
	AF*	US-6,962,978-A1	11-08-2005	Pepinsky et al.	
	AG*	US-6,372,207	04-16-2002	Tepper et al.	·
	AH*	US-5,906,816	05-25-1999	Soos et al.	
	Al*	US-6,060,450	05-09-2000	Soos et al.	
	AJ*	US-20030007969-A1	01-09-2003	Lobb et al.	
	AK*	US-20050214253-A1	09-29-2005	Whitty et al.	
	AL*	US-20050107277-A1	05-19-2005	Lin et al.	

	FOREIGN PATENT DOCUMENTS					
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Initials*	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	ן די
	BA	WO-01/77137	10-18-2001			
	BB	WO-00/23472	04-27-2000			
	ВС	WO-00/23114	04-27-2000			
	BD	WO-98/28007	07-02-1998			
	BE	WO-04/28472	04-08-2004			
	BF	WO-03/61577	07-31-2003			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, and/or country where published.		T²		
	CA	Schwarting, A. et al. "Prophylaxis and Therapy of Severe Lupus Nephritis by Interferon-beta Treatment." Kidney Blood Press. Res. 2001, Vol 24, No. 4-6, p. 218.		
	СВ	International Search Report for PCT/US03/22440, mailed July 2, 2004.		
	СС	May and Sehgal. "On the Relationship Between Human Interferon Alpha 1 and Beta 1 Genes." J. Interferon Res. 1985, Vol. 5, p. 521-26.		

Examiner	Date	
Signature	Considered	



PTO/SB/08a/b (07-05)
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First Named Inventor	Roy R. Lobb		
Art Unit	N/A		
Examiner Name	Not Yet Assigned		
Attorney Docket Number	BII-001.01		

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	Factor-related Apoptosis-inducing Ligand (TRAIL) Expression on Human T Cells: A Novel	
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CE	V.J. Cavanaugh et al. "Inhibition of Hepatitis B virus Replication During Adenovirus and	
	Cytomegalovirus Infections In Transgenic Mice." J. Virol. 1998, Vol. 72, No. 4, p. 2630-37.	
CF	T. Vial et al. "Immune-mediated Side-Effects Of Cytokines In Humans." Toxicology. 1995, Vol.	
	105, No. 1, p. 31-57.	
CG	J. Imanishi "Interferon-alpha, Beta, Gamma." Gan To Kagaku Ryoho. 1994, Vol. 21, No. 16. p.	
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CK	Y. Shiratori et al. "Different Turnover Rate Of Hepatitis C Virus Clearance by Different	
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CL	S.E. Krown. "Interferon Treatment Of Renal Cell Carcinoma. Current Status And Future	
	Prospects." Cancer. 1987, Vol. 59, No. 3 Suppl., p. 647-51.	
CM	S. Mani et al. "Recombinant Beta-Interferon In The Treatment Of Patients With Metastatic	
	Renal Cell Carcinoma." Am. J. Clin. Oncol. 1996, Vol. 19, No. 2, p. 187-89.	
CN	C. Scoponi et al. "Long-lasting Complete Remission Of Pulmonary Metastases Consequent To	
ı	Renal Cell Carcinoma Obtained With Interferon-Beta Therapy: Review Of The Literature And	
	A Case Report." Tumori. 1995, Vol. 81, No. 3, p. 201-3.	
co	E.C. Borden et al. "Biological and Clinical Effects of Interferon-Beta Ser at Two Doses." J	
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	Effect Of Antibodies to Very Late Antigen-4 or VCAM-1 on Glomerular Injury." J. Immunol.	
	1999, Vol. 162, No. 9, p. 5519-27.	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.